

Center for Devices and Radiological Health

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# CDRH 2012 Strategic Priorities



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## INTRODUCTION

As we release our 2012 Strategic Priorities, we are proud to report on our accomplishments from 2011. We completed work on fifty action items in 2011. Highlights of the significant amount of work our staff accomplished in 2011 include:

- We released the [Plan of Action for Implementation of 510\(k\) and Science Recommendations](#) and completed many of actions in the Plan as well as undertook several additional efforts to improve our pre-market programs.  
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276286.htm>
- We released a report, "Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health," to provide a broad overview of the many scientific activities in which our staff are currently engaged, as well as what we see as important regulatory science targets in the future as science and technology continue to evolve.  
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM274162.pdf>
- We issued guidance on the Agency's regulatory expectations for in vitro diagnostic devices and therapeutic products that are developed together such that the therapeutic product depends on the diagnostic test to direct the use of the therapeutic product.  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm>
- We played a critical role on the establishment of the International Medical Device Regulators Forum (IMDRF; see <http://www.imdrf.org/>), a voluntary group of medical device regulators from around the world who will charge future directions in medical device regulatory harmonization.
- We completed the pre-market reviewer competencies and began a Reviewer Certification Program (RCP) pilot.  
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm270858.htm>
- We launched an initiative to identify and promote best-quality device manufacturing practices. This includes a report, "Understanding Barriers to Medical Device Quality," that reviews the challenges that the FDA and industry face in supporting well-integrated, best-quality manufacturing practices and strategies that industry and the FDA can take to overcome these barriers.  
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm277272.htm>
- We completed database requirements and began the design and development phase of a unique device identification system. We also sent the draft rule to OMB.  
<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201104&RIN=0910-AG31>
- We launched the Innovation Initiative, which proposed actions the Agency could take to help accelerate and reduce the cost of development and regulatory evaluation of innovative medical devices in a way that maintains or improves patient safety and is based on sound science.  
<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm>

To complete this work our staff went above and beyond their already demanding workload. This is a remarkable achievement.

In 2012 we will focus on completing or continuing the work we already started in our four priority areas. This document identifies broad strategies that CDRH will implement in 2012 in alignment with those four priority areas: (1) Fully Implement a Total Product Life Cycle Approach, (2) Enhance Communication and Transparency, (3) Strengthen Our Workforce and Workplace, and (4) Proactively Facilitate Innovation to Address Unmet Public Health Needs. It includes timeframes associated with each strategy, and specific actions we will take to meet those goals or make significant progress towards achieving those goals.

Working together to achieve these goals we can take important steps to further our mission to protect and promote the public health.

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## **PRIORITY I. FULLY IMPLEMENT A TOTAL PRODUCT LIFE CYCLE APPROACH**

CDRH will make well-supported regulatory decisions that take into consideration all of the relevant information available to the Center, at any stage of a product's life cycle to assure the safety, effectiveness, and quality of medical devices, and the safety of non-device radiation-emitting products.

### **Strategy 1.1. Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions**

CDRH will have in place strong, mutually reinforcing organizational components supported by integrated knowledge management systems, that work with a unity of effort toward our mission, and that are equipped to anticipate and address changes in the scientific and global-market landscape.

#### **1.1.1. Strengthen Premarket Review**

**Goal 1.1.1.1. In 2012, CDRH will continue implementation of the action plan to improve our premarket programs.**

- ❖ By April 1, 2012, begin the Triage of Pre-market Submissions Pilot to increase submission review efficiency and better manage the pre-market review workload.
- ❖ By December 31, 2012, publish a proposed rule to clarify the circumstances under which CDRH could rely on clinical studies conducted in and for other countries.
- ❖ By December 31, 2012, finalize all guidance documents issued as part of the plan to improve our premarket programs.
- ❖ By December 31, 2012 conduct an evaluation of CDRH staffing, infrastructure, policies, and practices pertaining to medical software.

**Goal 1.1.1.2. In 2012, CDRH will continue to take steps to address Class III device types currently allowed to enter the market through the 510(k) process.**

- ❖ By December 31, 2012, clear within CDRH proposed rules for all remaining Class III pre-amendment medical devices.

#### **1.1.2. Address Challenges Associated with Globalization**

**Goal 1.1.2.1. By September 30, 2012, CDRH will have in place mechanisms to further harmonization efforts and exchange medical device information with foreign regulatory authorities.**

- ❖ By March 31, 2012, hold the first meeting of the International Medical Device Regulators Forum.
- ❖ By September 30, 2012, participate in at least two harmonization activities with one or more foreign regulatory authorities.

### 1.1.3. Enhance Compliance Capability

**Goal 1.1.3.1. By December 31, 2012, CDRH will begin to implement its business-case-for-quality initiative to address best-quality manufacturing practices, including mechanisms for FDA-industry engagement and increased transparency of device quality data.**

- ❖ By June 30, 2012, select and begin to implement 2012 actions in support of the business-case-for-quality initiative.
- ❖ By December 31, 2012, select actions to be implemented in 2013 in support of the business-case-for-quality initiative.

**Goal 1.1.3.2. By October 31, 2012, CDRH will take steps to enhance the efficiency and clarity of the medical device and radiation-emitting product recall processes.**

- ❖ By September 30, 2012, develop methods and procedures for the systematic analysis and use of medical device recall information.
- ❖ By October 31, 2012, develop and begin to implement criteria for terminating recalls, including online posting of recall terminations.

### 1.1.4. Enhance Collaboration Through Reorganization

**Goal 1.1.4.1. In 2012, CDRH will continue to implement its reorganization plan to enhance and integrate premarket, postmarket, and compliance information and functions.**

- ❖ By December 31, 2012, provide at least two updates to staff on the status of the reorganization.

### 1.1.5. Implement a Knowledge Management Strategic Plan

**Goal 1.1.5.1. By October 31, 2012, CDRH will develop and begin to implement a Knowledge Management Strategic Plan to make the best use of information collected or developed by CDRH.**

- ❖ By March 31, 2012, hire a Knowledge Management Director.
- ❖ By October 31, 2012, finalize and begin to implement CDRH's Knowledge Management Strategic Plan.

### 1.1.6. Assess Real World Device Performance

**Goal 1.1.6.1. By October 31, 2012, CDRH will develop a comprehensive strategy to assess real world device performance.**

- ❖ By April 30, 2012, post on the web a proposed strategy to assess real world device performance and seek public input.
- ❖ By October 31, 2012, develop a comprehensive framework for the timely evaluation and management of significant postmarket signals.

### 1.1.7. Enhance CDRH's Quality Assurance Program

**Goal 1.1.7.1. By December 31, 2012, strengthen CDRH quality assurance framework for periodically auditing the Center's regulatory programs and decisions and providing recommendations for improvement.**

- ❖ By June 30, 2012, hire an Assistant Director for Quality Assurance.
- ❖ By December 31, 2012, implement a Center-wide quality assurance program.

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## PRIORITY 2. ENHANCE COMMUNICATION AND TRANSPARENCY

To improve public health and foster trust among our employees and with our constituencies, CDRH will provide meaningful and timely information about the products we regulate and the decisions we make, through strategic outreach and systems that support transparency and two-way communication.

### Strategy 2.1. Enhance Communication and Transparency with Our Stakeholders

CDRH will develop and distribute timely information about medical device and radiation-emitting electronic products that is useful to our external constituencies, using methods that meet their needs, while giving them opportunities to engage in a dialogue with the Center about the issues important to them.

**Goal 2.1.1. In 2012, CDRH will continue to take steps to strengthen information exchange and improve gathering feedback from our external constituencies.**

- ❖ By December 31, 2012, take steps towards establishing a national forum for engaging with patients, consumers and health care professionals in a dialogue about issues of interest to them.

### Strategy 2.2. Improve Internal Communications

CDRH staff will have access to timely information about what the Center is working on, completed projects, organizational information and will have opportunities to engage dialogue, share ideas and make suggestions to enhance CDRH's ability to successfully achieve our mission.

**Goal 2.2.1. By December 31, 2012, CDRH will establish an internal communication program to improve communication of information and ideas to and from CDRH Staff.**

- ❖ By September 30, 2012, issue standard operating procedures (SOPs) for sharing information with CDRH Staff.
- ❖ By December 31, 2012, with input from staff, develop and begin to implement a plan to improve internal communication.

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## **PRIORITY 3. STRENGTHEN OUR WORKFORCE AND WORKPLACE**

CDRH will be a thriving organization with the knowledge, skills, and technical expertise we need to fulfill our mission; a collaborative employee culture; efficient administration of CDRH programs; and a workplace environment that supports productivity.

### **Strategy 3.1. Continue to support the Life Cycle Approach to CDRH Employee Education**

CDRH employees will have access to high quality educational tools and programs, assuring that we accomplish our mission and meet the anticipated demands of the future.

**Goal 3.1.1. By December 31, 2012, CDRH will launch the Experiential Learning Program (ELP) to enhance premarket reviewer knowledge of how medical devices are designed, manufactured, and utilized by providing real-world learning opportunities.**

- ❖ By March 31, 2012, begin the ELP pilot.
- ❖ By December 31, 2012, fully implement the ELP.

**Goal 3.1.2. By December 31, 2012, CDRH will launch the CDRH Leadership Enhancement and Development Program (LEAD) to provide CDRH managers and supervisors information and tools to assure effective leadership.**

- ❖ By March 31, 2012, begin the LEAD pilot.
- ❖ By December 31, 2012, fully implement LEAD.

### **Strategy 3.2. Enhance Employee Satisfaction**

CDRH will recognize the value of our employees and provide a workplace environment that supports productivity.

**Goal 3.2.1. By September 30, 2012, CDRH will make recommendations on how to adequately recognize good employee performance and address poor performance.**

- ❖ By February 28, 2012, form an internal, cross-Center, staff-led work group to develop recommendations.
- ❖ By September 30, 2012, share with Center staff the work group's recommendations and seek their input.

**Goal 3.2.2. By September 30, 2012, CDRH Offices will make recommendations on what resources are necessary to ensure staff are successful in performing their work.**

- ❖ By May 31, 2012, Offices will solicit recommendations from staff on what resources are necessary to ensure staff are successful in performing their work.
- ❖ By September 30, 2012, Offices will share their recommendations and an action plan for implementation with staff.



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## **PRIORITY 4. PROACTIVELY FACILITATE INNOVATION TO ADDRESS UNMET PUBLIC HEALTH NEEDS**

CDRH will further enhance our efforts to anticipate emerging technological trends and public health challenges and partner with federal and external stakeholders to facilitate the development of innovative, safe and effective medical devices and advance regulatory science.

### **Strategy 4.1. Foster the Development of Innovative Medical Devices**

CDRH will work with our federal government partners and external constituencies to facilitate the development of innovative, safe and effective medical devices.

**Goal 4.1.1. By September 30, 2012, CDRH will create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators.**

- ❖ By March 31, 2012, using the Entrepreneurs in Residence Program, begin to pilot the Innovation Pathway 2.0.
- ❖ By September 30, 2012, assess the implementation of the Innovation Pathway 2.0.

### **Strategy 4.2. Further Develop a Personalized Medicine Program**

CDRH will work collaboratively with our federal government partners and external constituencies to assure the appropriate regulatory oversight of therapeutics and diagnostics when their safety and effectiveness are intimately tied to one another.

**Goal 4.2.1. By September 30, 2012, CDRH will continue to develop policies and procedures to assure that safe and effective diagnostic products that are either innovative themselves or provide innovative uses reach the public.**

- ❖ By June 30, 2012, clear within CDRH the final guidance on Companion Diagnostics.
- ❖ By December 31, 2012, clear within CDRH draft guidance on co-development of drugs or biologics and devices.

### **Strategy 4.3. Strengthen Regulatory Science**

CDRH will work collaboratively with our federal government partners and external constituencies to advance medical device regulatory science.

**Goal 4.3.1. By December 31, 2012, CDRH will have in place mechanisms to enable collaborative work between FDA, our federal government partners and external constituencies to advance medical device regulatory science.**

- ❖ By December 31, 2012, establish a public-private partnership between industry, the FDA, and academia to advance regulatory science.

**Goal 4.3.2. By September 30, 2012, CDRH will expand computer modeling and simulation efforts to support regulatory science.**

- ❖ By September 30, 2012, finalize a strategy for validating and incorporating computer models that are part of the Virtual Physiological Patient Project into a publicly accessible library that can be used in device development and regulatory applications.